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10/021,793	12/12/2001	Stephen Ray Wurzbarger	RSSW13	3436

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EXAMINER

JIANG, SHAOJIA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/021,793

Applicant(s)

WURZBURGER, STEPHEN RAY

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on November 15, 2004 wherein claims 1-6 are cancelled.

Currently, claims 7-27 are pending in this application.

Claims 7-27 are under examination on the merits.

#### Priority

This application is a continuation of Serial No. 09307100 now patented 6,331,514 which is a continuation in part of Serial No. 08994547 now abandoned.

However, the patent 09307100 (6,331,514) and 08994547 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the instant claims of this application since both parent applications are not seen to disclose the solution comprising organic solvent and the volume percentage range of the ingredients as claimed herein.

Therefore, the effective filing date of the instant claims is deemed to be the filing date of the instant application, December 12, 2001. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

In clarifying the priority date of the instant claims, applicant should note or address whether the art rejections are prior to the priority date of the instant claims and whether said art occurred more than one year prior to said priority date. Applicant will

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note that the art rejections are under both 35 U.S.C. § 102(a) and 102(b) because the priority date of the instant claims is in question.

The terminal disclaimer filed on May 14, 2003, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. 6,331,514 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Therefore, the obviousness-type double patenting rejection as being unpatentable over claims 1-5 of U.S. Patent No. 6,331,514 is withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7-27 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: "the solution of claim 1".

Note that claim 1 is cancelled. Insertion of the recitation of solution of claim 1 would be considered.

In order to expedite prosecution, claims 7-27 will be examined inserting the recitation of solution of claim 1, as have apparently been intended.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-15 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular and specific metal salts such as those recited in claims 16-22, and specific acids, the particular and specific organic solvent such as those in claim 8, in the solution herein, does not reasonably provide enablement for any substances or compounds represented by “a metal, a metal hydride, a metal oxide, a metal hydroxide and an acid having an anion capable of forming an insoluble salt with said metal” and organic solvent selected in sufficient concentration to one of emulsify and dissolve said carrier...” recited in the claims herein.

These recitations, “a metal, a metal hydride, a metal oxide, a metal hydroxide and an acid having an anion capable of forming an insoluble salt with said metal” and organic solvent selected in sufficient concentration to one of emulsify and dissolve said carrier...” are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

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undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdAplis 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a solution for sterilizing a surface of skin of a human.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims may reasonably encompass not only those known but also unknown "a metal, a metal hydride, a metal oxide, a metal hydroxide and an acid having an anion capable of forming an insoluble salt with said metal" and organic solvent selected in sufficient concentration to one of emulsify and dissolve said carrier..." as of the instant filing date.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function,

as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case, "a metal, a metal hydride, a metal oxide, a metal hydroxide and an acid having an anion capable of forming an insoluble salt with said metal" and organic solvent selected in sufficient concentration to one of emulsify and dissolve said carrier...", recited in the instant claims are purely functional distinction. However, the specification merely provides particular salts and acids and organic solvents.

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as

discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Further, these recitations may broadly encompass those known and **unknown** "a metal, a metal hydride, a metal oxide, a metal hydroxide and an acid having an anion capable of forming an insoluble salt with said metal" and organic solvent selected in sufficient concentration to one of emulsify and dissolve said carrier..." as of the instant filing date, as discussed above. These recitations broadly encompass those known and **unknown** as of the instant filing date. Note those **future known** compounds yet to be discovered and/or made. Hence, those unknown or future known compounds encompassed by claim 1 herein must require to additional or future research to discover, establish or verify their usefulness. Therefore, as indicated in the previous Office Action, the skilled artisan has to exercise **undue experimentation** to practice the instant invention.

The presence or absence of working examples and the quantity of experimentation necessary:

It is noted that only several particular metal salts and acids and organic solvents were tested in the working examples of the specification (see page 11-19 of the specification). Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active agents or compounds in the claimed composition.



Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search and undue experimentation for the embodiments of any known and unknown compounds having those functions encompassed in the instant claims suitable to practice the claimed invention.

*Genentech*, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be applied to a human skin, with no assurance of success.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the ranges of the pH value "between 15 and 1.8". There is insufficient antecedent basis for this limitation in the claim since the independent claim 7 which claim 14 is dependent from merely recites "pH to below 2.5".

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wachman et al. (US 5407949, PTO-892) in view of Applicant's admission regarding the prior art in the specification (see page 2) further in view of Andrews et al. (US 5569461, PTO-892) or Jooste (US 5389384, PTO-892).

Wachman et al. discloses that an exemplified sterilizing composition for against a wide range of virus, bacteria, and fungi (see col. 14-22), comprise water, sodium nitrate, the instant quaternary ammonium compounds, isopropanol (also known isopropyl alcohol) and carrier, with the specific amounts (see the typical composition in the table at col.4 line 23-32; col.5-8, Example A-B and 1 at col.10-11; claims 1-12). Wachman et al. disclose that oxalic acid is useful in the sterilizing composition therein (see col.8 line 66). Wachman et al. also disclose that the composition therein is useful between pH 4-9 (see abstract).

Wachman et al. does not expressly disclose that the pH is below 2.5. Wachman et al. does not expressly disclose the employment of lactic acid in the composition therein with the volume percent range for salts and acids.

Applicant's admission regarding the prior art at page 2 lines 6-7 of the specification teaches that "[t]he acid MicroWater has a been found to have commercially viable bactericidal properties when used in the lowest pH range (2.5) attainable (reported)" (emphasis added). Note that "MicroWater<sup>TM</sup> distributed by Optimum Health Institute, San Mateo, Cal." See page 2. Thus, pH range below 2.5 for sterilizing or disinfecting solutions is known in the art.

Andrews et al. teaches that lactic acid as an antifungal, antibacterial agent is useful for disinfecting and antimicrobial composition therein which also comprise glycerol. See col.1 line 41; Example 5 at col.6 line 55-65.

Jooste teaches that oxalic acid is used in the sterilizing or disinfecting composition (see col.5 line 15). In particular, Jooste teaches that acidic solutions therein are in the pH range of about 2-6 (see col.6 line 33-35).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to adjust the pH below 2.5, and to optimize the amount of the salts and acid in volume percentage, and add lactic acid in the composition of Wachman et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to adjust the pH below 2.5, since it has been known that the solution with the pH range below 2.5 has bactericidal properties. Jooste also teaches

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that acidic solutions therein are in the pH range of about 2-6, overlapping with the instantly claimed. Thus, one of ordinary skill in the art would have reasonably adjusted the pH below 2.5, based on the known and available knowledge.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the amount of the salts and acid in volume percentage since specific amounts in weight percentages of the salts and acids are known in the sterilizing compositions of Wachman et al. Thus, the calculation known amounts of known active agents and conversion the weight percentage to volume percentage are considered well within the competence level of an ordinary skilled artisan in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One having ordinary skill in the art at the time the invention was made would have been motivated to add lactic acid or oxalic acid to the sterilizing compositions of Wachman et al since lactic acid or oxalic acid is known to have disinfecting and antimicrobial properties. It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Further, mineral oil and fragrance are old and well-known to be useful in skin caring or cosmetic compositions.

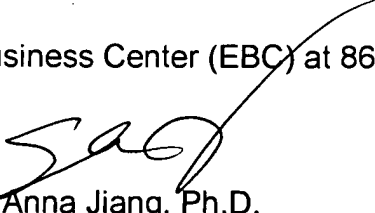
Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Primary Examiner  
Art Unit 1617  
February 24, 2005